Attachment 2

510(k) SUMMARY

SEP 19 2012

1. **Contact Information**

Submitter's name:	Walk on Wheels Australia Pty, Ltd. 260 Leitchs Road Brendale, Queensland 4500 Australia
Contact Person:	Sheila Ramerman, RAC SJR Associates
Date prepared:	September 4, 2012

2. **Device name:**

Trade name: Walk on Wheels HS-3500 Electric Aisle Wheelchair
Common name: Powered wheelchair
Classification name: Wheelchair, powered, ITI

3. **Legally Marketed Predicate Device:**

HEARTWAY Attendant-Controlled Power Chair, TC1, K071006

4. **Device Description:**

The Walk on Wheels HD-3500 Electric Aisle Wheelchair is a power wheelchair designed to transport elderly or disabled persons on/off an airplane. It has a base with four wheels, a padded seat with adjustable/foldable armrests and seatbelt, adjustable/removable foot rests with a leg band, and hand controls located at the back of the wheelchair allowing an attendant to control the chair. It can be disassembled for transport and is provided with an off-board battery charger.

5. **Intended Use/Indications for Use:**

The Walk on Wheels HS-3500 Electric Aisle Wheelchair is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person on/off an airplane or within the airport terminal. It is also suited for use in other narrow constrained spaces. It is not intended to be used during flight.

6. **Substantial Equivalence Comparison:**

The device features of the Walk on Wheels HS-3500 and the HEARTWAY TC1 are very similar. Both are attendant controlled and battery powered. Off-board battery chargers are provided with both powered wheelchairs. Both can be disassembled for transport. The target population is similar and the use parameters are similar.

7. Non-Clinical Testing

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles,* July 1995 were conducted and the results are included in the submission. All testing was successful.

EMC testing was performed, and the HS-3500 and its battery charger passed the EMC testing.

Applicable ANSI/RESNA WC-1 and WC-2 standards and ISO 7176 standards were used for performance testing. The HS-3500 complies with the cited standards.

8. Clinical Testing

Clinical testing is not included in this submission.

9. Conclusions

The non-clinical testing demonstrates that the HS-3500 Electric Aisle Wheelchair performs as designed and intended. Comparison of specifications with the predicate device demonstrates that any differences in specifications or technology do not raise new questions of safety or effectiveness. The HS-3500 Electric Aisle Wheelchair is substantially equivalent to the predicate device in design, function, and indications for use/intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 19 2012

Walk on Wheels Australia Party, Limited
% SJR Associates
Ms. Sheila Ramerman, RAC
Principal Consultant
927 Throne Drive
Eugene, Oregon 97402

Re: K120405
Trade/Device Name: Walk on Wheels HS-3500 Electric Aisle Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 10, 2012
Received: September 12, 2012

Dear Ms. Ramerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use

510(k) Number (if known): _____

Device Name: Walk on Wheels HS-3500 Electric Aisle Wheelchair

Indications for Use:

The Walk on Wheels HS-3500 Electric Aisle Wheelchair is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person on/off an airplane or within the airport terminal. It is also suited for use in other narrow constrained spaces. It is not intended to be used during flight.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120405